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K110800

SEP 27 2011

5. 510(k) Summary

General Information

Date Compiled	September 21, 2011
Classification	Class II, 21 CFR § 888.3040, Smooth or threaded metallic bone fixation fastener. Product code MBI
Trade Name	Meta-Lock™ Suture Anchor System
Submitter	Tarsus Medical, Inc. 465 Fairchild Drive Suite 230 Mountain View, CA 94043
Contact	Nicholas Mourlas President and CEO Tel: (650) 237-0070 Fax: (650) 237-0071

Intended Use

The Tarsus Medical Meta-Lock Suture Anchor System is intended for fixation of suture to bone for the indications listed below:

SHOULDER:	Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, Deltoid repair
ANKLE:	Lateral instability, medial instability, achilles tendon repair/reconstruction, Midfoot reconstructions
FOOT:	Hallux valgus reconstruction
WRIST:	Scapholunate ligament
HAND:	Ulnar or lateral collateral ligament reconstruction
ELBOW:	Biceps tendon reattachment
KNEE:	Extra capsular repairs; reattachment of : medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tendonesis; patellar ligament and tendon avulsions.

Predicate Device

GII QuickAnchor Plus K051989
Manufactured by Depuy Mitek

Device Description

The Meta-Lock™ Suture Anchor System is a suture anchor used for the reattachment of soft tissue to bone.

Materials

The Meta-Lock is comprised of Commercially Pure Titanium (Grade 2) conforming to ASTM F67-06, Stainless Steel (Biodur 108 Alloy) conforming to ASTM F2229, and polyester suture.

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Testing

The non-clinical tests performed by the company include anchor tensile testing, system tensile testing, cyclic testing, magnetic resonance (MR) testing, galvanic corrosion testing, simulated movement testing, and simulated use testing. The test results demonstrate that the Meta-Lock is substantially equivalent to the legally marketed predicate device.

Summary of Substantial Equivalence

Tarsus Medical, Inc. believes the Meta-Lock Suture Anchor System is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to the existing legally marketed predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Tarsus Medical, Inc.
% Nicholas Mourlas
465 Fairchild Drive, Suite 230
Mountain View, CA 94043

SEP 27 2011

Re: K110800
Trade/Device Name: Meta-Lock™ Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: August 16th, 2011
Received: August 17th, 2011

Dear Dr. Mourlas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ewin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): This application K110800

Device Name: Meta-Lock™ Suture Anchor System

Indications for Use: The Tarsus Medical Meta-Lock Suture Anchor System is intended for fixation of suture to bone for the indications listed below:

SHOULDER:	Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis; deltoid repair
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Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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510(k) Number K110800